



Jun 28 2011
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Attorneys for Defendants Ethicon, Inc.
and Johnson & Johnson

IN RE PELVIC MESH/GYNECARE
LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, ATLANTIC COUNTY

CIVIL ACTION

CASE NO. 291

Master Case No. L-6341-10

Honorable Carol E. Higbee, P.J.Cv.

**MASTER ANSWER AND JURY DEMAND
OF DEFENDANTS ETHICON, INC. AND
ETHICON WOMEN'S HEALTH &
UROLOGY**

Defendant Ethicon, Inc., on its own behalf and on behalf of its division, Ethicon Women's Health & Urology (jointly, "Ethicon"), in answer to the plaintiffs' Master Long Form Complaint, states as follows:

1. Except to admit that Ethicon, Inc. is a wholly owned subsidiary of Johnson & Johnson with its principal place of business in Somerville, New Jersey and to admit that Ethicon Women's Health and Urology is a division of Ethicon, Inc., Ethicon denies each and every allegation of the Master Long Form Complaint as it pertains to Ethicon and leaves plaintiffs to their proofs.

SEPARATE DEFENSES

FIRST DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted.

SECOND DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

THIRD DEFENSE

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

FOURTH DEFENSE

Plaintiffs' claims are barred for lack of personal jurisdiction.

FIFTH DEFENSE

The Complaint must be dismissed because the plaintiffs provided insufficient process.

SIXTH DEFENSE

The Complaint must be dismissed because the plaintiffs provided insufficient service of process.

SEVENTH DEFENSE

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because plaintiffs may lack standing and/or capacity to bring such claims.

EIGHTH DEFENSE

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

NINTH DEFENSE

Venue in Atlantic County is improper in any individual case in which the plaintiff does not reside in Atlantic County or otherwise cannot establish an independent basis for venue in Atlantic County under New Jersey law and any such plaintiff's case should be dismissed on this basis.

TENTH DEFENSE

Venue in this Court is improper, and this matter should be dismissed on intra-state or interstate forum non conveniens grounds.

ELEVENTH DEFENSE

Venue in this Court is improper because Atlantic County may not be a proper or fair venue for Ethicon given Atlantic County's over-exposure to prior mass tort pharmaceutical cases. This matter should be dismissed on this basis.

TWELFTH DEFENSE

Certain of plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

THIRTEENTH DEFENSE

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

FOURTEENTH DEFENSE

The improper joinder of plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the applicable state.

FIFTEENTH DEFENSE

Ethicon is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case.

SIXTEENTH DEFENSE

Plaintiffs have failed to plead fraud, fraudulent concealment, constructive fraud and misrepresentation with the particularity required under Rule 4:5-8(a) of the Rules Governing the Courts of the State of New Jersey and the common law of New Jersey, any rule or statute of any other state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SEVENTEENTH DEFENSE

Ethicon specifically pleads as to plaintiffs' fraud, fraudulent concealment, constructive fraud and misrepresentation claims, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTEENTH DEFENSE

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device

Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the Gynecare products at issue¹ are regulated by the U.S. Food and Drug Administration (“FDA”) under the Medical Device Amendments, 21 U.S.C. § 360c, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations.

NINETEENTH DEFENSE

At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360c, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and plaintiffs’ claims are accordingly barred.

TWENTIETH DEFENSE

Plaintiffs’ claims against Ethicon are expressly and/or impliedly preempted by federal law, including but not limited to the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

TWENTY-FIRST DEFENSE

Plaintiffs’ claims are barred because Ethicon complied with all applicable state and federal statutes regarding the Gynecare products at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of

¹ The phrase “Gynecare products at issue” includes the products collectively referenced in Paragraph 13 of the Master Long Form Complaint as “Defendants’ Pelvic Mesh Products.”

the Code of Federal Regulations. In the event that plaintiffs' claims are not barred, Ethicon is entitled to a presumption that the Gynecare products at issue are free from any defect or defective condition as the plans or design for the Gynecare products at issue or the methods and techniques of manufacturing, inspecting, and testing the Gynecare products at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the Gynecare products at issue or the methods and techniques of manufacturing, inspecting, and testing the Gynecare products at issue were adopted.

TWENTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder.

TWENTY-THIRD DEFENSE

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA.

TWENTY-FOURTH DEFENSE

Any claims by plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon to petition the government.

TWENTY-FIFTH DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for medical devices.

TWENTY-SIXTH DEFENSE

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by plaintiffs is subject to the exclusive regulation of the FDA.

TWENTY-SEVENTH DEFENSE

Plaintiffs' claim for punitive damages is barred because the Gynecare products at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the Gynecare products at issue.

TWENTY-EIGHTH DEFENSE

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for any of the Gynecare products at issue.

TWENTY-NINTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the Gynecare products at issue provided a benefit to users of such products and greatly outweighed any risk created by using such products, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

THIRTIETH DEFENSE

Ethicon made no express or implied representations or warranties of any

kind to plaintiffs, nor did plaintiffs rely on any representations or warranties made by Ethicon to others. To the extent plaintiffs relied upon any representations or warranties, such reliance was unjustified.

THIRTY-FIRST DEFENSE

Any express or implied warranties alleged to have been made by Ethicon were disclaimed.

THIRTY-SECOND DEFENSE

Ethicon did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Ethicon, and/or by plaintiffs' failure to give Ethicon timely notice of the alleged breach of warranty and an opportunity to cure. Ethicon further specifically pleads as to any breach of warranty claim all affirmative defenses available to Ethicon under the Uniform Commercial Code, as enacted in the State of New Jersey or any other state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

THIRTY-THIRD DEFENSE

Ethicon specifically pleads as to any claim alleging a violation of consumer protection laws, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

THIRTY-FOURTH DEFENSE

The injuries resulting from the use of the Gynecare products at issue, were not foreseeable to Ethicon given the state of scientific knowledge and state of the art at

the time of the alleged injuries. At all times relevant, the Gynecare products at issue conformed to state-of-the-art specifications and state of scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of the FDA.

THIRTY-FIFTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the Gynecare products at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages plaintiffs seek to recover herein.

THIRTY-SIXTH DEFENSE

Plaintiffs’ claims are barred, in whole or in part, because Ethicon acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its products.

THIRTY-SEVENTH DEFENSE

At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

THIRTY-EIGHTH DEFENSE

Plaintiffs’ inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

THIRTY-NINTH DEFENSE

Plaintiffs’ claims are barred in whole or in part because the Gynecare products at issue were consistent with and/or exceeded consumer expectations.

FORTIETH DEFENSE

Plaintiffs' claims are barred in whole or in part because the Gynecare products at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.

FORTY-FIRST DEFENSE

Adequate and complete warnings and instructions were provided with the Gynecare products at issue. The Gynecare products at issue were neither defective nor unreasonably dangerous when used according to their Instructions for Use.

FORTY-SECOND DEFENSE

At all relevant times, the warnings and instructions accompanying the Gynecare products at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the products were presumptively adequate.

FORTY-THIRD DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

FORTY-FOURTH DEFENSE

Ethicon is not liable to the plaintiffs because the end user of the Gynecare products at issue, plaintiffs' physician(s), were sophisticated users of the products.

FORTY-FIFTH DEFENSE

Ethicon states that the sole proximate cause of the injuries and/or damages alleged by plaintiffs was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way liable. Plaintiffs are not, therefore, entitled to recover from Ethicon in this action. As

to plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of plaintiffs, if any, Ethicon expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of the applicable states.

FORTY-SIXTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by plaintiffs' own fault, which bars or proportionately reduces Ethicon's liability, if any, for plaintiffs' alleged damages.

FORTY-SEVENTH DEFENSE

The plaintiffs voluntarily and unreasonably chose to encounter known dangers.

FORTY-EIGHTH DEFENSE

The liability of Ethicon, if any, for plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of the applicable states.

FORTY-NINTH DEFENSE

In the event Ethicon is held liable to plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Ethicon is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

FIFTIETH DEFENSE

There is no causal relationship between Ethicon's conduct and the injuries

and damages alleged by plaintiffs in the Complaint.

FIFTY-FIRST DEFENSE

At all times mentioned herein, plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of plaintiffs bars in whole or in part the damages which plaintiffs seek to recover herein.

FIFTY-SECOND DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the Gynecare products at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said products.

FIFTY-THIRD DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were not legally caused by the Gynecare products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FIFTY-FOURTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the Gynecare products at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility.

FIFTY-FIFTH DEFENSE

Ethicon expressly denies any third party engaging in the acts alleged by plaintiffs was acting as Ethicon's agent or servant, at the instruction of Ethicon, or within its control. Therefore, plaintiffs' claims, to the extent they seek to recover for

the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

FIFTY-SIXTH DEFENSE

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the products at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.

FIFTY-SEVENTH DEFENSE

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

FIFTY-EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

FIFTY-NINTH DEFENSE

The claims of plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to properly preserve evidence necessary to the determination of the claim.

SIXTIETH DEFENSE

Plaintiffs' claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or

files for bankruptcy at some point in the future, the claims of any such plaintiff may be “property of the bankruptcy estate” which should be prosecuted by the bankruptcy trustee rather than the plaintiff, or, if not disclosed by the plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

SIXTY-FIRST DEFENSE

Some or all of plaintiffs’ claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of the applicable states.

SIXTY-SECOND DEFENSE

To the extent plaintiffs’ claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

SIXTY-THIRD DEFENSE

Plaintiffs’ alleged damages, if any, are barred in whole or in part by plaintiffs’ failure to mitigate such damages.

SIXTY-FOURTH DEFENSE

The sale, labeling and marketing of the Gynecare products at issue in this litigation is not, and was not, likely to mislead or deceive the public.

SIXTY-FIFTH DEFENSE

The Gynecare products at issue were altered after the products left the control, custody and possession of Ethicon, and said alteration relieves Ethicon of any and all liability.

SIXTY-SIXTH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

SIXTY-SEVENTH DEFENSE

Plaintiffs' claims are barred in whole or in part under Section 402A, comments j and k of the Restatement (Second) of Torts.

SIXTY-EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

SIXTY-NINTH DEFENSE

Any recovery by plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

SEVENTIETH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

SEVENTY-FIRST DEFENSE

The Complaint fails to state facts sufficient to entitle plaintiffs to an award of punitive damages.

SEVENTY-SECOND DEFENSE

Plaintiffs' claims for punitive damages are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), pursuant to *McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10 (App. Div.), *certif. granted in part and denied in part*, 196 N.J. 597 (2008), *appeal dism'd as improv. granted*, 200 N.J. 267 (2009) (holding that a punitive damages claim brought pursuant to PLA's exception in N.J.S.A. 2A:58C-5c

was preempted under the *Buckman* decision). The *McDarby* decision is dispositive in this case, requiring that plaintiffs' punitive damages claims be dismissed on this basis.

SEVENTY-THIRD DEFENSE

No act or omission of Ethicon was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SEVENTY-FOURTH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Ethicon's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and the applicable states.

SEVENTY-FIFTH DEFENSE

The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the

corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon's conduct within the State where each plaintiff resides, or in any other way subject Ethicon to impermissible multiple punishment for the same alleged wrong.

SEVENTY-SIXTH DEFENSE

Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

SEVENTY-SEVENTH DEFENSE

With respect to plaintiffs' demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007),

and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

SEVENTY-EIGHTH DEFENSE

Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the applicable states.

SEVENTY-NINTH DEFENSE

Ethicon denies that it is indebted in any sum whatsoever to plaintiffs and will demonstrate to this Court and the jury it is not responsible for any injuries or damages that may have occurred according to the allegations set forth in plaintiffs' Complaint.

EIGHTIETH DEFENSE

Ethicon specifically pleads as to plaintiffs' claims for punitive damages, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-FIRST DEFENSE

Ethicon specifically pleads as to plaintiffs' strict liability claims, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-SECOND DEFENSE

Ethicon specifically pleads as to plaintiffs' negligence claims, including plaintiffs' separate negligence claim under Connecticut law, all affirmative defenses

available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-THIRD DEFENSE

Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

EIGHTY-FOURTH DEFENSE

Ethicon reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

EIGHTY-FIFTH DEFENSE

Ethicon reserves all available defenses permitted by the applicable law, in accordance with the procedure set forth in Paragraph 12 of Case Management Order No. 3.

EIGHTY-SIXTH DEFENSE

Several of plaintiffs' claims are subsumed by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1, *et seq.*

EIGHTY-SEVENTH DEFENSE

Plaintiffs' claims are barred and/or limited by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.*

EIGHTY-EIGHTH DEFENSE

Plaintiffs' claims are barred by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-3(a)(1).

EIGHTY-NINTH DEFENSE

Plaintiffs' claims are barred by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-3(a)(2).

NINETIETH DEFENSE

Plaintiffs' claims are barred by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-3(a)(3).

NINETY-FIRST DEFENSE

Because the products at issue were accompanied by an adequate warning or instruction, plaintiffs' claims are barred by New Jersey case law and the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1, *et seq.*

NINETY-SECOND DEFENSE

Plaintiffs' claims are barred and/or limited by the New Jersey Comparative Negligence Act, N.J.S.A. 2A:15-5.5 *et seq.*

NINETY-THIRD DEFENSE

Plaintiffs' claims for exemplary and/or punitive damages are barred, in whole or in part, by the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9 *et seq.*

NINETY-FOURTH DEFENSE

Without reference to or waiver of any conflicts of law arguments by Ethicon, plaintiffs cannot state a claim under the New Jersey Consumer Fraud Act because all claims for harm caused by a product are governed by the New Jersey Products Liability Act, pursuant to the New Jersey Supreme Court's decision in *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 948 A.2d 587, 596 (N.J. 2008).

WHEREFORE, Ethicon denies that it is liable to the plaintiffs for damages or any other relief requested in the "Prayer for Relief" section of plaintiffs' Complaint, including the paragraph beginning "WHEREFORE" and subparagraphs (1)-(9) thereto, Ethicon prays that:

- (1) plaintiffs take nothing by reason of their Complaint;
- (2) the Complaint be dismissed in its entirety and that a Judgment against plaintiffs and in favor of Ethicon be entered;
- (3) Ethicon be awarded its costs and expenses; and
- (4) this Court award Ethicon any other and general or specific relief as this Court may deem just and proper.

Of Counsel:

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By: 

Kelly S. Crawford

Dated: June 28, 2011

*Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson*

DEMAND FOR TRIAL BY JURY

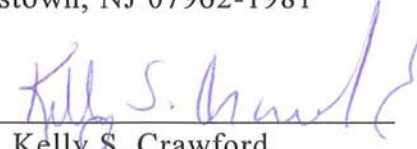
Ethicon demands a trial by jury of twelve of all claims triable as of right
by jury.

Of Counsel:

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By:


Kelly S. Crawford

Dated: June 28, 2011

*Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson*

RULE 4:5-1 CERTIFICATION

The undersigned counsel for Defendants Ethicon, Inc. and Johnson & Johnson hereby certifies that this case is among many cases involving pelvic mesh products manufactured by Ethicon, Inc. which have been assigned for centralized case management to the Honorable Carol Higbee, Superior Court, Law Division, Atlantic County, by Order dated September 13, 2010 and captioned In re Pelvic Mesh/Gynecare Litigation, Case No. 291. The undersigned further certifies that Defendants' counsel is unaware of the identities of any other persons or entities who should be joined in the within action.

Of Counsel:

Christy D. Jones, Esq.
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By: _____


Kelly S. Crawford

Dated: June 28, 2011

*Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson*

DESIGNATION OF TRIAL COUNSEL

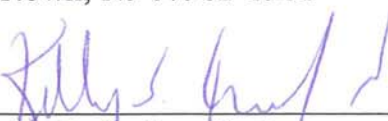
Pursuant to the provisions of Rule 4:25-4, the Court is advised that Kelly Strange Crawford, Esq. is designated as trial counsel for Defendants Ethicon, Inc. and Johnson & Johnson.

Of Counsel:

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Dated: June 28, 2011

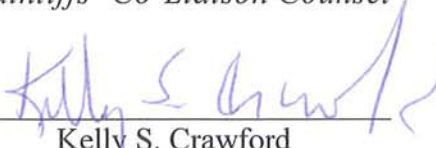
*Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson*

CERTIFICATION OF SERVICE

I certify that on this date I caused the attached Master Answer and Jury Demand of Defendants Ethicon, Inc. and Ethicon Women's Health and Urology to be served by LexisNexis File & Serve and Federal Express upon:

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